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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,225	11/07/2001	Giampiero Valleta	C36226/127436	5568

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,225	VALLETA ET AL	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-11,16-19 and 22-31* is/are pending in the application.

4a) Of the above claim(s) *1-4,11,16-19,22-24,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10,25-28 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *5/16/05* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed Feb 22, 2005. Upon entering the amendment, the claims 8-9 are amended and the claims 5-7 12-15 and 20-21 are canceled. New claim 31 is added.

2. The claims 1-4, 8-11, 16-19 and 22-31 are pending.

It is noted that newly added claim 31 includes non-elected species(i.e. inflammation). Since elected species is pruritis(itching), the claim 31 have been examined only to the extent that they read on use of the elected species in the claimed method. All remaining(or portions thereof) not drawn to the elected species are withdrawn from further consideration as being non-elected.

821 Treatment of Claims Held To BeDrawn to Nonelected Inventions

Claims held to be drawn to nonelected inventions, including claims to nonelected species, are treated as indicated in MPEP § 821.01 through § 821.03.

The propriety of a requirement to restrict, if traversed, is reviewable by petition under 37 CFR 1.144 . *In re Hengehold*, 440 F.2d 1395, 169 USPQ 473 (CCPA 1971).

All claims that the examiner holds as not being directed to the elected subject matter are withdrawn from further consideration by the examiner in accordance with 37 CFR 1.142(b). See MPEP § 809.02(c) and § 821.01 through § 821.03. The examiner should clearly set forth in the Office action the reasons why the claims withdrawn from consideration are not readable on the elected invention. Applicant may traverse the requirement pursuant to 37 CFR 1.143. If a final requirement for restriction is made by the examiner, applicant may file a petition under 37 CFR 1.144 for review of the restriction requirement.

1. The elected invention(previously), claims 8-10 25-28 are examined based on the merit are presented for the examination and non-elected claims(previously) 1-4, 11, 16-19, 22-24 and 29-30 are maintained as withdrawn.

3. During a telephone conversation with Mr. Brown, Steven on May 12, 2005, allowable subject matter is indicated and amendment is suggested to accommodate the changes so that the application can be placed under allowable condition, , but did not result in an agreement being made, see interview summary attached.

Claim Objections

4. Claims 8-10, 25-28 and 31 objected to because of the following informalities: Thruout the claims, the term "pruritis" is not inconsistently use whereas "pruritis" in claim 8 is written "pruritus" in claims 9-10. Although both terms" pruritis" and "pruritus" have a definition "itching sensation", it would be better if the claims have consistent terminology to avoid any unpredicted confusion. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

Claims 8-10, 25-28 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or preventing pruritis from reoccurrence or specific pruritis(e.g. pruritis associated with renal insufficiency such as vulvar pruriti), does not reasonably provide enablement for complete prevention of pruritis. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 the court recited eight factors:

1) *The nature of the invention:*

The instant invention is drawn to a treating/preventing pruritis, using an effective amount of nicotinic acid or nicotinamide and an effective amount of riboflavin, and excludes administering any other vitamin agent and any other anti-inflammatory agent.

2) *The state of the prior art:*

As the state of art recognizes, there are numerous path-etiologic factors(e.g.bio-pathways and pathogens) involved in pruritis.

The state of the art recognizes that the significance of particular drug treatment for modifying different aspects of biological activity cannot be predicted a priori and furthermore. Especially pruritis can be the symptoms of various disorders(secondary manifestations), and thus it can not be completely prevented or treated unless primary disorders are treated or prevented. The state of the art also recognizes that a single drug treatment is effective for all the pathogens or etiological factors which may be responsible for different pruritis and selectively effective and used

in the treatment/prevention from reoccurrence of the specific pruritis but not for all the pruritis or complete prevention.

3) *The relative skill of those in the art:*

The relative skill of the those in the art is high.

4) *The predictability of the art:*

The high degree of unpredictability in the treatment of pruritis is well known in the art. A slight change in the structure of the drug would drastically change its influence on receptor binding activity.

For a pharmaceutical composition containing multiple active ingredients or carriers having different chemical structures and modes of actions, their interaction, co-action, e.g. synergism etc. is even more unpredictable.

5) *The breadth of the claims:*

Applicant's assertion that the inventive compounds, its composition would be useful for treating/preventing all the possible pruritis, or complete prevention of pruritis does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability and the limited working examples.

6) *The amount of guidance/working examples:*

The specification only exemplifies specific pruritis such as vulvar pruritis and prevention from reocurrence for certain period time(e.g. 2-3 months), see examples at pages 15- 23. The specification fails to include

any specific teaching showing efficacy of the said drugs against pruritis caused by path-etiological factors and specific area of pruritis involved.

Applicant also fails to show complete prevention from any occurrence of pruritis. The specification provides lack of evidential support substantially where any skilled artisan can not clearly understand how the claimed invention(i.e. complete prevention/ treatment of all types of pruritis nor complete prevention for any specific pruritis) is made at the time of the invention with the information provided and thus, the claims are considered not enabled with the information given.

7) *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the specification, one of ordinary skill in the art, even with high degree of skill, would not be able to use the composition as claimed without undue experimentation except for treating specific pruritis or preventing from reocurrence using the claimed composition.

The true fact of the state of the art in cancer therapy is expressed well, "The significance of particular drug treatment for modifying different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study " to determine the efficacy against pruritis.

Note: Applicant should be reminded about new matter associated with any future amendment, if there is any.

Allowable Subject Matter

2. Claims 8-10, 25-28 and 31 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action.

3. Allowable subject matter indicated during the telephone interview.

4. As noted in the previous office action, because primary reference(Scivoletto(US 6248763)) teaches the pruritis treatment using nicotinic acid and secondary reference (Patric US 5496827) teaches the combination of nicotinic acid and riboflavin where riboflavin potentiates the nicotinic acid's activity, it would have been obvious to use combination to treat pruritis. However, both references(alone or in combination) fails to teach pruritis associated with renal insufficiency and particular amount ration between active ingredients which is critical in this case because Patric(US'827) states that excessive nicotinic acid would cause unwanted pruritis.

Thus, the allowable subject matter (if rewritten or amended to overcome 112 1st rejection) would be allowable because it is free from the prior art of record.

Conclusion

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
May 16, 2005
Art unit 1618